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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANGELL, JON E	
ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,050	BRATZLER ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,21,31 and 36-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17,21,31 and 36-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 6/20/2006 is acknowledged and has been entered.

Claims 1-17, 21, 31, 36-71 are currently pending in the application and are addressed herein.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-5, 7, 12-17 (including linking claims 1, 8, 9, 37, 41, 43-47) drawn to a method for treating a subject having or at risk of developing a cancer by administering an immunostimulatory oligonucleotide, including a non-CpG oligonucleotide and a poly-G nucleic acid and further administering a cancer medicament that is a chemotherapeutic agent, classified in class 514, subclass 44.

II. Claims 2-5, 10-17, (including linking claims 1, 8, 9, 37, 41, 43-47) drawn to a method for treating a subject having or at risk of developing a cancer by administering an immunostimulatory oligonucleotide, including a non-CpG oligonucleotide and a poly-G nucleic acid and further administering a cancer medicament that is an immunotherapeutic agent, classified in class 514, subclass 44.

III. Claims 2-5, 12-17 (including linking claims 1, 8, 9, 37, 41, 43-47) drawn to a method for treating a subject having or at risk of developing a cancer by administering an immunostimulatory oligonucleotide, including a non-CpG

oligonucleotide and a poly-G nucleic acid and further administering a cancer medicament that is an cancer vaccine, classified in class 514, subclass 44.

IV. Claims 6, 31 (only to the extent that claim 31 reads on a non-CpG nucleic acid) (including linking claims 1, 8, 9, 37, 41, 43-47) drawn to a method for treating a subject having or at risk of developing a cancer by administering an immunostimulatory oligonucleotide, including a non-CpG oligonucleotide and a poly-G nucleic acid and further administering a cancer medicament that is an hormone therapy, classified in class 514, subclass 44.

V. Claim 21, drawn to a method of preventing an allergic reaction in a subject receiving a blood transfusion by administering an immunostimulatory nucleic acid, classified in class 514, subclass 44.

VI. Claim 31 (only to the extent that claim 31 reads on a CpG nucleic acid), drawn to a method of treating a subject having or at risk of developing cancer comprising administering a CpG nucleic acid and a cancer medicament that is a hormone therapy, classified in class 514, subclass 44.

VII. Claims 36, 38-40, 42, drawn to a device for delivering an immunostimulatory nucleic acid to a subject, classified in class 604, subclass 890.1.

VIII. Claims 48-50, drawn to a kit comprising an immunostimulatory oligonucleotide, classified in class 536, subclass 23.1.

IX. Claims 51-56, 62-69, drawn to a method for treating cancer by administering a ligand for a pattern recognition receptor, classified in class 514, subclass 2.

X. Claims 57-61, drawn to a method comprising coating a medical device with a composition comprising a ligand for a pattern recognition receptor, classified in class 424, subclass 2.1.

XI. Claims 70, 71, drawn to a kit comprising a ligand for a pattern recognition receptor, classified in class 530, subclass 300.

2. Claims 1, 8, 9, 37, 41, 43-47 link(s) the inventions of Groups I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 8, 9, 37, 41, 43-47. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

NOTE: Claim 2 contains an improper Markush Group because it includes (1) a chemotherapeutic agent, (2) an immunostimulatory agent, and (3) a cancer vaccine. As set forth in *In re Harnisch* (631F.2d 716 206 USPQ 300 (CCPA 1980), see MPEP 803.02, unity of invention exists for all species in a Markush group if the species (1) have a common utility, **AND** (2) share a substantial structural feature disclosed as being essential to that utility (emphasis

added). In the instant case, the species of the Markush group have a common utility, but they do not share a substantial structural feature disclosed as essential to that utility. Thus, the chemotherapeutic agent, immunostimulatory agent and the cancer vaccine have been separated into patentably distinct groups.

Also, Claim 31 contains an improper Markush Group because it includes (1) a CpG nucleic acid, and (2) a non-CpG nucleic acid. As set forth in *In re Harnisch* (631F.2d 716 206 USPQ 300 (CCPA 1980), see MPEP 803.02, unity of invention exists for all species in a Markush group if the species (1) have a common utility, **AND** (2) share a substantial structural feature disclosed as being essential to that utility (emphasis added). In the instant case, the species of the Markush group have a common utility, but they do not share a substantial structural feature disclosed as essential to that utility. Thus, the CpG nucleic acid and the non-CpG nucleic acid have been separated into patentably distinct groups.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-IV, VI, IX are directed to related processes of treating cancer. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation because each invention utilizes a different and unrelated therapeutic agent. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions I-IV, VI, IX are directed to processes that are related to the process of Invention V. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect because Inventions I-IV, VI and IX are drawn to treating cancer while V is drawn to treating an allergic reaction. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions I-VI are related to Invention VII as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus, such as using a simple syringe to inject the therapeutic agent into the subject. Furthermore, the apparatus as claimed can be used to practice another and materially different process, for instance the apparatus could be used in any of the processes of Inventions I-VI, as of which are different processes.

6. Invention VIII is related to Inventions I-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

§ 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product such as any of the processes of Inventions I-VI, as of which are different processes. Alternatively, the nucleic acid of the kit could be used to immunize an animal to raise antibodies specific for the nucleic acid. Alternatively, the nucleic acid could be used as a probe (or as a template for making a probe) where the probe can be used to assay for the presence of a complementary nucleic acid sequence in a sample.

Inventions VII and VIII are directed to a product that are unrelated to the process of Invention IX. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, VII and VIII are drawn to a device for delivering an immunostimulatory nucleic acid and a kit comprising an immunostimulatory nucleic acid, while IX is drawn to a method of treating cancer using a ligand for a pattern recognition receptor. It appears that the ligand is not a nucleic acid. Thus the device and kit are not used in or made by the process of IX.

7. Inventions IX and X are directed to related process. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect because a method of treating cancer is materially different in design mode of operation, function, and effect compared to a method of coating a medical device. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

8. Inventions X and XI are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the product cannot be used in, or made by, the process of coating a medical device.

9. Inventions IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product. For instance, the product can be administered to an animal to produce antibodies that are specific for the ligand.

10. Inventions I-VI and X are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VII and VIII directed to products unrelated to the process of Invention X. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the device

and kit of VII and VII cannot be used in, or made by, the process of coating a medical device with a ligand.

Invention XI is directed to a product unrelated to the processes of Inventions I-VI. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, kit comprising a ligand and other elements is not used in, or made by, the processes of I-VI.

11. Inventions VII, VIII are directed to products related to Invention XI. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect because the kit comprising the ligand is structurally and functionally distinct from the device and kit comprising an immunostimulatory nucleic acid of VII and VIII. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims 3, 7, 15 which are directed to patentably distinct species of chemotherapeutic agents. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 7 are generic.

This application contains claim 4 which is directed to patentably distinct species of immunotherapeutic agents. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4 are generic.

This application contains claim 5 which is directed to patentably distinct species of cancer vaccines. The species are independent or distinct because claims to the different species

recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 5 are generic.

This application contains claims 9, 45, 67 which are directed to patentably distinct species of cancer. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-17, 31, 51-56, 62-69 are generic. To be fully responsive, Applicants must pick a cancer that is explicitly encompassed by a claim of the elected Group.

This application contains claim 52 which is directed to patentably distinct species of cancer therapies. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 51, 52 are generic.

This application contains claim 59 which is directed to patentably distinct species of implanted devices. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 57-59 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species from each species group to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that

a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
Art Unit 1635